

## **FDA 510k CONSULTING AND SUBMISSION AGREEMENT**

This FDA 510K Consulting and Submission Agreement ("Agreement") is entered into as of the 26<sup>th</sup> day of December, 2018, to be effective on the 26<sup>th</sup> day of December, 2018, by and between Induction Therapies a Kentucky Corporation ("Company"), and Ingunes, LLC ("Ingunes"), a Delaware Corporation and Ingunes may be referred to jointly hereinafter as the "Parties".

Company is engaged in the sale of a medical microneedling device ("Device").

Company and Ingunes desire to enter into a relationship whereby the Parties will work together to submit a 510k application requesting clearance of the Device by the United States Food & Drug Administration ("FDA").

**NOW THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, it is mutually agreed as follows:

All pricing included in this document is in United States Dollars (USD).

Ingunes will act as a liaison between Company and the testing laboratory to contract for testing costs and to ensure timely commencement and completion of each stage of the testing process.

That the following testing is already in progress, and that the testing facility has already been paid in full for same:

- Biocompatibility Testing, which includes a panel of 5 tests – Cytotoxicity, Irritation, Skin Irritation, Acute systemic toxicity, and Pyrogenicity

That the Biocompatibility Testing results are scheduled to be completed as follows:

1. Cytotoxicity Test 12.28.28
2. Skin Sensitization Test 1.17.19
3. Intracutaneous Reactivity Test 1.5.19
4. Acute Systemic Toxicity Test: 1.5.19
5. Pyrogenicity Test: 12.26.18

That Ingunes has not been paid its fee for arranging the testing and ensuring timely completion of same, that the total fee owed to Ingunes for this work is \$1,593.00, and that this fee shall be paid to Ingunes upon execution of this Agreement.

The Parties agree that the following process is currently in progress:

- Sterilization of the needle cartridges per ISO 11135

The Parties further agree that the Company has paid fifty percent (50%) of the cost of the needle sterilization (\$16,520.00), and shall pay the remaining fifty percent (50%) of the cost of the sterilization (\$16,520.00) upon completion of the sterilization process. The payments for the sterilization process shall be paid directly to Ingunes via wire transfer unless otherwise agreed to by the Parties.

That Ingines has already located and yet to contract the following testing at the following pricing, but that the following testing has not yet commenced:

- IEC Panel – (ES/EMC/SW Life Cycle/Usability) per IEC 60601-1, 62304, 6060-1-1-6, 60601-1-2: **\$20,818.00**
- IEC Panel - Battery testing per IEC 62133 and UN 38.3: **\$13,148.00**
- EtO Sterilization Validation per ISO-11737: **\$10,214.00**
- Sterility Panel - Package Integrity (Visual inspection as per ASTM F1886, Measurement of seal width as per ASTM F1886/F1886M, Dye leak test as per ASTM F1929, Bubble test per ASTM F 2096) per ISO 11607: **\$1,856.00**
- Seal Strength (Heat Peel Seal Strength per ASTM F88 and per ASTM F88 and Burst test per ASTM F 1140): **\$1,856.00**
- Sterility Panel - Shelf Life – (Accelerated Aging for 90 days at elevated temperature condition per ASTM F-1980): **\$23,270.00**
- Sterility Panel - Shelf Life – Real time Aging for 2 years per ASTM F-1980: **\$6,952.00**
- Reprocessing Validation Test per ISO-17664: **\$15,090**
- Performance – Bench Test - Needle Dimension Analysis & Leak/Back Flow: **\$4,920.00**
- Transportation Validation Test: **\$7,000.00**

Testing will be carried out at recognized laboratories in India. The liaison/testing lab will charge 100% fee, if the Company cancels the testing work after it's started.

The above quoted price is only for testing as per the standards mentioned herein. If any additional standards or requirements are applicable, a revision to this proposal will be provided for acceptance.

That the above testing shall commence immediately upon completion of the sterilization process, and all remaining tests shall run concurrently, with the exception of the Animal Testing, which is addressed below. The above testing is expected to be completed within twelve (12) weeks of their commencement date and 2 years in case of real time testing.

The Company will provide the required samples and/or accessories, information (such as risk management file, user manuals, bill of materials, photos, electrical/electronic drawings, etc., as needed) and necessary supporting documentation in a timely manner as requested by the concerned laboratory to successfully complete the testing. The liaison will make an effort to get the actual testing and test report delivery schedule and share it with the Company.

It may not be possible for the testing laboratory to meet the above turnaround time in case of product failures, testing failures, modification delays etc., which is beyond the control of the liaison.

The above quotation is for testing the final finished device only and doesn't include testing of safety of critical components in case they are not already certified.

The above mentioned quotation is for testing laboratory charges for one cycle of testing and does not include re-testing the product in case of failures.

Testing may involve some destructive tests. During testing, it may be necessary to open, dis-assemble, remove components and also conduct chemical analysis from the sample and this must be acceptable to the Company/client. Liaison will not be liable for any damages caused to

the device or product during the testing.

That the Parties have not yet located a facility at which the device will undergo Animal Testing - non-clinical performance test. That the Device will undergo Animal Testing at a mutually agreed upon laboratory and that the Company shall advise Ingernes whether Ingernes needs to locate an approved laboratory no later than December 31, 2018.

That the consulting fee for preparing and filing the 510k Submission for the Device will be capped at \$35,000.00.

That the consulting fee for 510k Submission shall be paid in four (4) installments as follows:

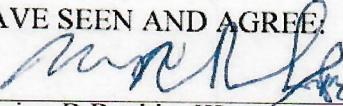
1. \$10,000.00 upon commencement of all remaining testing
2. \$10,000.00 upon completion of all remaining testing
3. \$10,000.00 upon submission of the 510k to the FDA
4. \$5000.00 upon clearance by the FDA of the device

That Ingernes charges an hourly rate of \$350.00 for Quality Assurance Review of all draft test reports. That Company agrees that Ingernes will review all draft test reports upon completion of all testing, and agrees to pay a fixed consulting fee at \$15,000.00.

That the payment for review of all draft test reports (not to exceed \$15,000.00) shall be paid upon review of the draft testing reports and confirmation that the testing is sufficient for use with the 510k submission.

If the scope of work changes or device fails the testing and re-testing is required or the test has to be repeated, there would be additional cost. If the scope of work changes, liaison will discuss it with the Company before proceeding any further.

HAVE SEEN AND AGREED:

  
Marion R Rankin, III,  
COO  
Induction Therapies, LLC

Date: 12-26-18

  
Krishnamurthy Govindaraj,  
President & CEO  
Ingernes, LLC

Date: 12-26-2018